guidelines regarding the risks to children of certain vaccines under section 313(a)(1)(B) and (b) of the National Childhood Vaccine Injury Act of 1986 is not redelegated by the Commissioner.

(6) Section 314 of the National Childhood Vaccine Injury Act of 1986–Review of warnings, use instructions, and precautionary information (42 U.S.C. 300aa–1 note).

(b) These officials may not further redelegate these authorities.

§ 5.201 Redelegation of the Center for Biologics Evaluation and Research Director's program authorities.

(a) The following officials are authorized to perform all the functions of the Director, Center for Biologics Evaluation and Research (CBER) with regard to program authorities for their respective areas:

(1) Deputy Directors, CBER.

(2) Associate Directors, CBER.

(3) Office Directors, CBER.

(4) Division Directors, CBER.

(b) These officials may not further redelegate these authorities.

§ 5.202 Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses, suspension of licenses, or revocation of licenses and certain notices of revocation of licenses.

(a) The Director and Deputy Directors, Center for Biologics Evaluation and Research are authorized to issue:

(1) Notices of opportunity for a hearing on proposals to deny approval or filing of applications for biologics licenses under § 601.4(b) of this chapter.

(2) Notices of opportunity for a hearing on proposals to revoke biologics licenses under § 601.5(b) of this chapter.

(3) Notices of revocation, at the manufacturer's request, of biologics licenses under §§ 601.5(a) and 601.8 of this chapter.

(4) Notices of revocation when the manufacturer has waived the opportunity for hearing under § 601.7(a) of this chapter.

(5) Notice of biologics license suspensions under § 601.6 of this chapter.

(b) These officials may not further redelegate these authorities.

§ 5.203 Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.

(a) The following officials are authorized to issue licenses under section 351 of the PHS Act (42 U.S.C. 262) for the propagation or manufacture and preparation of biological products as specified in the PHS Act, and to revoke such licenses at the manufacturer's request:

(1) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(2) Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Therapeutics Research and Review, and Office of Compliance and Biologics Quality, CBER.

(b) These officials may not further redelegate this authority.

§ 5.204 Notification of release for distribution of biological products.

(a) The following officials are authorized to issue written notices of release for distribution of licensed biological products under subchapter F (parts 600 through 680.31) of this chapter:

(1) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(2) The Director and Deputy Directors, Office of Compliance and Biologics Quality (OCBQ), CBER.

(3) The Director and Deputy Director, Division of Manufacturing and Product Quality, OCBQ, CBER.

(b) These officials may not further redelegate this authority.

Subpart E—Food and Cosmetics; Redelegations of Authority

§ 5.300 Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, nutrient content claims, and health claims.

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) under sections 409 and 721 of the act (21 U.S.C. 348 and 379e) regarding the issuance of notices of filing (including notices of extension of, or reopening of, the comment period), and of voluntary withdrawal, of petitions